Section II (Remarks)

A. Summary of Amendment to the Claims

Independent claim 74 and 95 have been amended to add the limitation that the balloon "in an inflated state is non-pillowed and spheroidal in shape." Such amendment is supported by the original application, for example, at paragraph [0024] ("Such methodology may be employed to form a low-pressure balloon article of a non-pillowed, generally spherical or flattened spherical character, in which the respective half-sections of the balloon are readily fabricated and mated to form the product balloon article.") No new matter within the meaning of 35 U.S.C. 132(a) has been introduced by the foregoing amendments.

B. Response to Claim Rejections Under 35 USC §102(e)

In the February 22, 2007 Final Office Action, claims 74-108 were rejected under 35 USC §102(e) as being anticipated by U.S. Patent No. 6,976,950 to Connors, et al. ("Connors"). Such rejections are traversed in application to the claims as amended herewith.

1. Law Regarding Anticipation Rejections

"Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." *W.L. Gore & Assocs. v. Garlock*, 721, F.2d 1540, 220 USPQ 303 at 313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). It is not enough that the prior art reference disclose all the claimed elements in isolation. Rather, "anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim." *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (emphasis added). Further, "[u]nder 35 U.S.C. § 102, anticipation requires that ... the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public." *Akzo, N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986).

2. Disclosure of Connors

Connors discloses various methods and apparatuses for attenuating or baffling transient pressure waves in various organs and systems of the body, including cardiovascular, pulmonary, renal/urological, gastrointestinal, hepatic/biliary, gynecological, central nervous,

musculoskeletal, otorhinolaryngical and ophthalmic organs and systems. Connors, col. 1, lines 17-25. Preferred aspects are directed to treatment of disorders of the urinary tract caused by sudden fluctuations of intravesical pressure, to ameliorate symptoms and discomfort associated with incontinence, urgency, frequency, interstitial cystitis, irritable bladder syndrome and neurogenic bladders. Id., lines 26-34.

Connors describes a device having a compressible element that is placed within the urinary bladder of a human patient, in a manner that allows the compressible element to act as a pressure accumulator or attenuator or to attenuate transient pressure events. Id., col. 9, lines 40-43 & col. 10, lines 48-50. An inflatable container includes a flexible wall that contains a compressible media such as a gas. Id., col. 11, lines 6-31. A flexible wall comprises first and second components bonded together along a seam. Id., col. 11, lines 28-32. Various sealing techniques, such as ultrasonic, radiofrequency, adhesive, or heat sealing, may be used. Id., col. 13, lines 12-15.

Connors refers to various methods of forming materials for such attenuation devices, including "extrusion to prepare sheets, plugs, or tubular structures" (e.g., col. 16, line 63 – col. 17, line 7; col. 19, lines 27-29); "injection mold[ing] to fabricate intricately designed parts," (col. 19, lines 29-30); "compression mold[ing] to prepare films" (col. 19, lines 30-31); "dip-molded or extruded" (col. 22, lines 41-43); or "lamination, coextrusion, ... [or] spray molding" (col. 23, lines 62-67).

Connors teaches a variety of device shapes, as indicated by the following passages reproduced below:

> The devices used in embodiments of the present invention may take many shapes. In some instances it may be desirable for manufacturing purposes to have the shape resemble dip-molded devices like condoms, surgical glove fingers, or children's toys. However, many other forms may provide better performance, in particular for providing baffling of pressure waves as well as attenuation of pressure spikes. Possible shapes for the attenuation devices include torroid like shapes, similar in form but not size to donuts and inner tubes; spoked wheel forms; horseshoe-like forms; mushroom-like forms; and banana-like forms.

(Col. 22, lines 29-40.)

FIG. 16A illustrates a toroidal embodiment, in which a plurality of central spokes are provided. FIG. 16B illustrates a crescent or "C" shaped attenuation device. Any of a variety of spherical, oval, elliptical or other shapes may be utilized such as those illustrated in FIG. 16C, in which the greatest length dimension of the inflated attenuation device is within the range of from about 1 to about 5 times the smallest cross-section. FIG. 16D illustrates a less arcuate variety as shown in FIG. 16B. In general, the attenuation device 66 may take any of a variety of forms which provides a sufficient volume to achieve the desired attenuation function, and which will minimize or eliminate risk of loss or obstructing outflow through the urethra.

(Col. 24, lines 14-26.)

The only specific disclosure by Connors of a balloon formed from peripherally bonded polymer sheets that *comes close to* spheroidal in shape is that of Figures 5-5A, which provide a balloon that appears round in top view, but is clearly **pillowed in shape** when viewed from the side. See Figures 5-5A of Connors (showing round appearance when viewed from above in Figure 5, and pillow-like appearance when viewed from the side in Figure 5A), with the corresponding brief descriptions of such Figures reproduced from Connors at col. 3, lines 56-60.

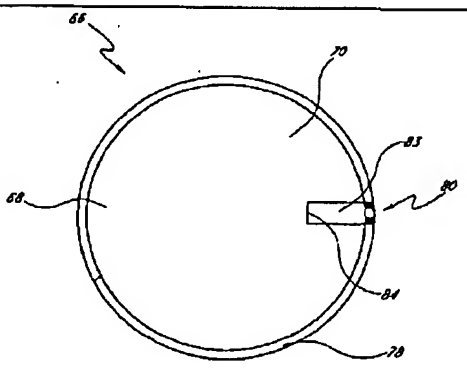


FIG. 5

FIG. 5 is a schematic **top plan view** of an inflatable attenuation device in accordance with one aspect of the invention. (Col. 3, lines 56-60.)

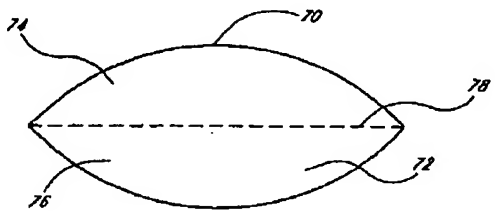


FIG. 5A

FIG. 5A is a **side elevational cross-section** through the attenuation device of FIG. 5. (Col. 3, lines 56-60.)

In the Detailed Description, Connors discusses the foregoing Figures as follows:

> The inflatable container 68 illustrated in FIGS. 5 and 5A comprises a flexible wall 70, for separating the compressible contents of the attenuation device 66 from the external environment. Flexible wall 70 comprises a first component 74 and second component 76 bonded together such as by a seam 78. In the illustrated embodiment, the first component 74 and second component 76 are essentially identical, such that the seam 78 is formed on the outer periphery of the inflatable container 68. Seam 78 may be accomplished in any of a variety of manners known in the medical device bonding arts, such as heat bonding, adhesive bonding, solvent bonding, RF or laser welding, or others known in the art.
>
> * * *
>
> In one embodiment, the attenuation device consists of an air cell consisting of 0.0018 inch thick polyurethane sheets that have been bonded together to form a 2⅜ inch **circle** ***in top view***.

Connors, col. 11, lines 28-39 & col. 12, line 66 – col. 13, line 2.

Connors fails to disclose any balloon that in an inflated state is non-pillowed and spheroidal in shape, formed from peripherally bonded sections of multilayer film.

3. Lack of Enablement or Teaching by Connors of Any Sheet-Based, Peripherally Bonded Spheroidal Balloon

The amended claims of the present application require, *inter alia*:

> **... a balloon that in an inflated state is non-pillowed and spheroidal in shape, formed from two vacuum thermoformed half-sections of a multilayer film comprising ... at least one layer of thermoplastic polymer film ...**

[with] the vacuum thermoformed half-sections [being] bonded to one another along peripheral portions thereof to form a peripheral seam ... .

Such combination of features is nowhere disclosed or suggested by Connors; that is, Connors contains no teachings that would enable one skilled in the art at the time the present invention was made to reproduce the subject matter of the amended claims. See the enclosed "Declaration of Tilak M. Shah Under 37 CFR 1.132" (hereinafter, "Shah Decl."), ¶ 9-12.

Although Connors makes *passing mention* to a spherically-shaped balloon (e.g., Connors, col. 11, lines 18-23), and Connors does disclose certain non-sheet-based methods (e.g., dip-molding, Col. 22, lines 41-43, or spray molding, col. 23, lines 62-67) suitable for forming spherical balloons, one skilled in the art would understand that not every balloon fabrication method mentioned by Connors is compatible with every particular balloon shape that is mentioned by Connors. (Shah Decl., ¶ 7.) Indeed, the specific disclosure by Connors (in Figures 5-5A and corresponding text) of a flat pillow-like balloon formed from peripherally circular sheets of material **not only represents a *lack of enablement* of, but also a *teaching away* from**, fabrication of a non-pillowed and spheroidal balloon formed from peripherally bonded polymer sheets. In a balloon formed by peripherally bonding two conventional non-elastic and non-thermoformed sheets, pillowing along the peripheral seam is the natural and inevitable result. (Shah Decl., ¶ 10-11 and Exhibits A1-A3.) Connors' specific disclosure of a balloon that appears round from top view (at Figure 5) but has a distinctly flat pillowed shape from the side view (at Figure 5A), cannot be taken as a teaching or enablement of the subject matter of the amended claims of the instant application.[1]

Vacuum thermoforming represents the only way known in the art for forming, from two peripherally bonded sections of non-elastic polymeric film, a balloon that in an inflated state is non-pillowed and spheroidal in shape. (Shah Decl., ¶ 9.) The use of vacuum thermoforming to

[1] To the extent that the Examiner should be tempted to formulate an obviousness rejection of the amended claims under 35 U.S.C. 103, it is noted that "[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); MPEP § 2141.02. In this regard, Connors' specific disclosure of a pillowed, non-spheroidal structure formed by peripherally sealing polymer sheets, to the exclusion of any non-pillowed spheroidal structure so formed, blunts any possible obviousness rejection.

fabricate balloons from polymeric sheets was **pioneered by the same inventor** as the present application, as evidenced by the issuance of U.S. Patent No. 6,712,832, which broadly claims methods for manufacturing low-pressure balloons from thin film polymeric materials, including the steps of heating the thermoplastic polymeric material thin film to a sufficient temperature for vacuum thermoforming thereof, forming first and second half-sections for a balloon from the thin film by vacuum suction, and bonding the first and second half-sections together along edges thereof. (Shah Decl., ¶ 13-14.) Notably, the application that matured into U.S. Patent No. 6,712,832 was not published (i.e., as U.S. Patent Application Publication No. 2003/0074017) until April 17, 2003 – which date is more than two weeks after the filing date of the instant U.S. Patent Application No. 10/815,282, and a month after the filing date of U.S. Patent Application No. 10/391,446 that matured into U.S. Patent No. 6,976,950 (Connors).[2] Because vacuum thermoforming represents the only way known in the art for forming, from two peripherally bonded sections of non-elastic polymeric film, a balloon that in an inflated state is non-pillowed and spheroidal in shape (Shah Decl., ¶ 9), the determination by the USPTO that the balloon fabrication methods involving vacuum thermoforming claimed in U.S. Patent No. 6,712,832 are novel and non-obvious over the prior art – coupled with the lack of public disclosure of the subject matter of U.S. Patent No. 6,712,832 prior to the filing date of Connors – is consistent with the notion that **Connors** (which fails to mention vacuum thermoforming) **cannot be fairly read or interpreted to disclose vacuum thermoforming or any other method for fabricating the subject matter of the amended claims** of the instant application.

Gastric balloons according to the amended claims represent an important advance in the art and are clearly distinct in character over prior art balloons. As indicated previously, in a balloon formed by peripherally bonding two conventional non-thermoformed and non-elastic sheets, pillowing along the peripheral seam is a natural and inevitable result. (Shah Decl., ¶ 10.) Photographs showing various views of a balloon formed from peripherally bonded non-thermoformed sheets of a multilayer film including a thermoplastic film layer are provided in Exhibits A1-A3 of the Shah Declaration. Such pillowing is undesirable in balloons intended for gastric use. (Id.) Pillowing creates involutions resulting in a profile, that in gastric use, tends to

[2] Due to these facts and the operation of 35 U.S.C. 103(c), neither U.S. Patent No. 6,712,832 nor the corresponding U.S. Patent Application Publication No. 2003/0074017 may be used in any obviousness rejection of the claims of the instant application.

abrade the lining of the stomach. (Id.) Moreover, pillowing tends to cause the seam of a gastric balloon to protrude outward, which in extreme cases can cause the seam to act as a cutting edge. (Id.) In contrast, a balloon corresponding to the subject matter of the amended claims of the instant application is non-pillowed, such that upon inflation thereof, the resulting seam between vacuum thermoformed half-sections is devoid of involutions and has a smooth and uniform shape. (Shah Decl., ¶ 10 and Exhibits B1-B3).

One skilled in the art at the time the present invention was made would not have looked to vacuum thermoforming for fabricating balloons from multi-layer polymer sheets. (Shah Decl., ¶ 13.) Vacuum thermoforming has traditionally been used with thick films that are homogeneous in character, such as to create packaging trays and the like. (Id.) The process of vacuum thermoforming tends to subject the working material to differential stresses as the material is deformed by heat and pressure to conform to the cavity of a vacuum thermoforming die. (Id.) Such differential stresses have been generally considered to be detrimental in application to multi-layer polymer sheets – particularly composite sheets formed from different material layers – due to the possibility of local or even bulk delamination of the individual layers under application of such stress. (Id.) Considering the desired end use of a balloon capable of retaining pressurized fluid, the risk of delamination would have led one of ordinary skill in the art at the time the invention was made to adopt a method other than vacuum thermoforming for forming a spherical balloon, such as dip molding or the like. (Id.) This is consistent with Connor' disclosure of dip molding (col. 22, lines 41-43) and balloons of spherical shape (col. 22, lines 29-40), since dip molding is well known as a method for forming spherical balloons. (Shah Decl., ¶ 13.)

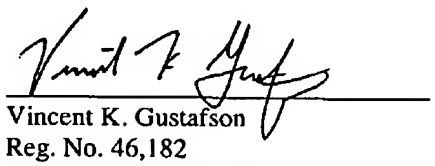
Restating one aspect of the foregoing arguments and evidence, Connors fails to enable the subject matter of the amended claims of the instant patent application. The Federal Circuit has unambiguously provided that "anticipation requires that ... the prior art reference be enabling, thus placing the allegedly disclosed matter in the possession of the public" *Akzo, N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986). Since Connors has failed to enable the subject matter of the amended claims, the claim rejections under 35 U.S.C. 102 premised on Connors cannot stand, and should be withdrawn.

Moreover, the subject matter of the amended claims is not obvious over the art. Neither vacuum thermoforming nor any other practicable method for forming a non-pillowed and spheroidal balloon formed from peripherally bonded polymer sheets was known in the art – as evidenced by Applicant's receipt of a prior U.S. patent 6,712,832 directed to such method. (Shah Decl., ¶ 9.) Considering the desired end use of a balloon capable of retaining pressure, the risk of causing delamination of the recited multi-layer sheets in a vacuum thermoforming process would ordinarily lead one in the art away from the use of such process. (Shah Decl., ¶ 13.)

CONCLUSION

Based on the foregoing arguments and evidence, all of Applicants' pending claims 74-108 are therefore patently distinguished over the art, and in form and condition for allowance. The examiner is requested to favorably consider the foregoing, and to responsively issue a Notice of Allowance. If any issues require further resolution, the examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same.

Respectfully submitted,



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Enclosure:
Declaration of Tilak M. Shah Under 37 CFR § 1.132 [12 pgs]

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